PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 1998 General Assembly.

SENATE ENROLLED ACT No. 10

AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-42-19-2 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 2. As used in this chapter, "drug" means the following:

(1) Articles or substances recognized in United States Pharmacopeial Convention, Inc.; The United States Pharmacopeia, Twenty-Second Edition (1990) or United States Pharmacopeial Convention, Inc.; The National Formulary, Seventeenth Edition (1990) as revised by United States Pharmacopeial Convention, Inc.; Supplement 1 to The United States Pharmacopeia, Twenty-Second Edition and The National Formulary, Seventeenth Edition (1990); **and any supplements printed after 1990.**

(2) Articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(3) Articles other than food intended to affect the structure or any function of the body of human beings or other animals.

(4) Articles intended for use as a component of any article specified in subdivision (1), (2), or (3).

(5) Devices.

SECTION 2. IC 16-42-19-11 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 11. **(a)** Except as provided in section 21 of this chapter, a person may not sell a legend drug unless either of the following conditions exist:

(1) **Except as provided in subsection (b),** the legend drug is dispensed by a pharmacist upon an original prescription or drug order **with the drug product specified on the prescription or drug order or by the authorization of the practitioner** and there is affixed to the immediate container in which the drug is delivered a label bearing the following:

(A) The name, address, and phone number of the establishment from which the drug was dispensed.

(B) The date on which the prescription for the drug was filled.

(C) The number of the prescription as filed in the prescription files of the pharmacist who filled the prescription.

(D) The name of the practitioner who prescribed the drug.

(E) The name of the patient, or if the drug was prescribed for an animal, a statement of the species of the animal.

(F) The directions for the use of the drug as contained in the prescription.

(2) The legend drug is delivered by the practitioner in good faith in the course of practice and the immediate container in which the drug is delivered bears a label on which appears the following:

(A) The directions for use of the drug.

(B) The name and address of the practitioner.

(C) The name of the patient.

(D) If the drug is prescribed for an animal, a statement of the species of the animal.

This section does not prohibit a practitioner from delivering professional samples of legend drugs in their original containers in the course of the practitioner's practice when oral directions for use are given at the time of delivery.

(b) Notwithstanding subsection (a)(1), the following apply:

(1) A pharmacist at a hospital licensed under IC 16-21 may fill a drug order for a legend drug with a drug product allowed under the hospital's policies and procedures for the use, selection, and procurement of drugs.

(2) A pharmacist who fills a prescription for a legend drug must comply with IC 16-42-22 and IC 25-26-16.

SECTION 3. IC 16-42-19-16 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 16. A person may not do any of the following:

(1) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug by any of the following:

(A) Fraud, deceit, misrepresentation, or subterfuge.

(B) The forgery or alteration of a prescription, drug order, or written order.

(C) The concealment of a material fact.

(D) The use of a false name or the giving of a false address.

(2) Communicate information to a physician in an effort unlawfully to procure a legend drug or unlawfully to procure the administration of a legend drug. Such a communication is not considered a privileged communication.

(3) Intentionally make a false statement in a prescription, drug order, order, report, or record required by this chapter.

(4) For the purpose of obtaining a legend drug, falsely assume the title of or represent oneself to be a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, or other person.

(5) Make or utter a false or forged prescription or false drug order or forged written order.

(6) Affix a false or forged label to a package or receptacle containing legend drugs. This subdivision does not apply to law enforcement agencies or their representatives while engaged in enforcing this chapter.

(7) Dispense a legend drug except as provided in this chapter.

SECTION 4. IC 16-42-22-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4. (a) As used in this chapter, "generically equivalent drug product" means a **multiple source** drug product:

(1) that contains an identical quantity of **identical** active ingredients in the identical dosage forms (but not necessarily containing the same inactive ingredients) that meet the identical physical and chemical standards in The United States Pharmacopeia (USP) ~~on July 1, 1987,~~ **described in IC 16-42-19-2, or its supplements,** as the prescribed brand name drug; and

(2) if applicable, for which the manufacturer or distributor holds either an approved new drug application or an approved abbreviated new drug application unless other approval by law or of the federal Food and Drug Administration is required.

(b) A drug does not constitute a generically equivalent drug product if it is listed by the federal Food and Drug Administration on **or after** July 1, 1987, as having actual or potential bioequivalence problems.

SECTION 5. IC 16-42-22-4.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 4.5. As used in this chapter, "practitioner" means any of the following:

(1) A licensed physician.

(2) A dentist licensed to practice dentistry in Indiana.

(3) A podiatrist licensed to practice podiatric medicine in Indiana.

(4) An optometrist who is:

(A) licensed to practice optometry in Indiana; and

(B) certified under IC 25-26-15.

(5) An advanced practice nurse licensed and granted the authority to prescribe legend drugs under IC 25-23.

SECTION 6. IC 16-42-22-5.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: **Sec. 5.5. Nothing in this chapter authorizes any substitution other than substitution of a generically equivalent drug product.**

SECTION 7. IC 16-42-22-8 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 8. **(a)** For substitution to occur for a prescription other than a prescription filled under the Medicaid program (42 U.S.C. 1396 et seq.) or the Medicare program (42 U.S.C. 1395 et seq.):

(1) the practitioner must sign on the line under which the words "May substitute" appear; **and**

(2) the pharmacist must inform the customer of the substitution.

(b) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

SECTION 8. IC 16-42-22-10 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 1999]: Sec. 10. (a) If a prescription is filled under the Medicaid program (42 U.S.C. 1396 et seq.) or the Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall substitute a generically equivalent drug product **and inform the customer of the substitution** if the substitution would result in a lower price unless:

(1) the words "Brand Medically Necessary" are written in the practitioner's own writing on the form; or

(2) the practitioner has indicated that the pharmacist may not substitute a generically equivalent drug product by orally stating that a substitution is not permitted.

(b) If a practitioner orally states that a generically equivalent drug product may not be substituted, the practitioner must subsequently forward to the pharmacist a written prescription with the "Brand

Medically Necessary" instruction appropriately indicated in the physician's own handwriting.

(c) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

SECTION 9. THE FOLLOWING ARE REPEALED [EFFECTIVE JULY 1, 1999]: IC 16-18-2-54; IC 16-42-22-2; IC 16-42-22-7.